



SANDRA SHEWRY
Director

State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

July 7, 2006

TO: California Physicians Administering Japanese Encephalitis Virus Vaccine
Inactivated (JE-VAX®)

FROM: Mark B. Horton, MD, MSPH
State Public Health Officer

SUBJECT: Continued Use of Japanese Encephalitis Virus Vaccine Inactivated
From July 1, 2006 – June 30, 2007

SUMMARY

Effective July 1, 2006, California law [Health and Safety Code Section 124172 subdivision (a)] provides that vaccines containing specific levels of mercury cannot be administered to pregnant women and young children, except under certain circumstances. The Secretary of the California Health and Human Services Agency has granted an exemption to this restriction for Japanese Encephalitis Virus Vaccine Inactivated (JE-VAX®) from July 1, 2006 to June 30, 2007. This exemption will allow this vaccine to continue to be administered to children younger than three years old and women who are pregnant. The exception was granted because of the dangers posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for residents of California seeking protection against Japanese Encephalitis.

Japanese Encephalitis Disease and Vaccine

Japanese Encephalitis, a mosquito-borne infection, is the leading cause of viral encephalitis (brain infection) in Asia and parts of Oceania. Unimmunized children in affected areas are at highest risk of infection. Most persons with encephalitis caused by the Japanese Encephalitis virus either die or have residual neurologic disease. Infection during pregnancy may cause miscarriage. There is currently no treatment for Japanese Encephalitis.

Major outbreaks of Japanese Encephalitis have been occurring in India and Nepal. Since July 2005, over 5,000 cases of suspected Japanese Encephalitis infection with at least 1,334 deaths (case fatality rate = 23.2 percent) have been reported from Uttar Pradesh Province in India, leading to a plan to immunize children in Uttar Pradesh between the ages of 1-12 years in 2006. In Nepal, over 2,800 suspected cases of Japanese Encephalitis have been reported, with at least 316 deaths (case fatality rate = 11.2 percent).

The Federal Food and Drug Administration has licensed only one vaccine against Japanese Encephalitis for use in the United States. The formal name of the vaccine is Japanese Encephalitis Virus Vaccine Inactivated, and its trade name is JE-VAX®. It is manufactured in Japan by The Research Foundation for Microbial Diseases of Osaka University ("BIKEN®") and distributed in the United States by sanofi pasteur, Inc.

Japanese Encephalitis Virus Vaccine Inactivated contains thimerosal as a preservative at a final concentration of 0.007%. The dose for children from 1-<3 years of age is 0.5 milliliters, which contain 17.5 micrograms of mercury. The dose for persons three years of age and older is 1.0 milliliters, which contain 35 micrograms of mercury. The mercury content of Japanese Encephalitis Virus Vaccine Inactivated exceeds the limit set by California Health and Safety Code Section 124172 subdivision (a) of 0.5 micrograms of mercury per 0.5 milliliter dose for vaccines (other than influenza vaccine) administered to young children and pregnant women in California on or after July 1, 2006. The bill which created this law, AB 2943 (Pavley, Chapter 837, Statutes of 2004), was signed in 2004 by Governor Arnold Schwarzenegger to ensure that pregnant women and children under age three have access to mercury-free vaccines.

Since 1993, The national Advisory Committee on Immunization Practices has recommended that Japanese Encephalitis Virus Vaccine Inactivated should be offered to persons spending a month or longer in endemic areas during the transmission season, to travelers to areas experiencing epidemic transmission and to persons whose activities, such as extensive outdoor activities in rural areas, place them at high risk for exposure.

(<http://www.cdc.gov/mmwr/preview/mmwrhtml/00020599.htm>.)

Exemption to California Mercury Free Vaccine Act

California Health and Safety Code Section 124172 subdivision (c) permits the Secretary of the Health and Human Services Agency to exempt the use of a vaccine from section 124172 subdivision (a) "if the secretary finds, and the Governor concurs, that...shortage of supply of a vaccine that would prevent children under three years of age and knowingly pregnant receiving the needed vaccine," making "necessary the administration of a vaccine containing more mercury than the maximum level set forth in subdivision (a)..." (http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_2901-2950/ab_2943_bill_20040928_chaptered.html)

The dangers posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for residents of California seeking protection against Japanese Encephalitis virus, an exemption has been granted from California Health and Safety Code Section 124172 subdivision (a) for Japanese Encephalitis Virus Vaccine Inactivated for the period of July 1 2006 through June 30, 2007. It may continue to be administered, as permitted by other State and federal laws, to children younger than three years old and women who are pregnant.

For additional information about this topic, please contact the California Department of Health Services Immunization Branch at (510) 620-3737 or www.getimmunizedca.org.

cc: DHS Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators

State of California—Health and Human Services Agency
Department of Health Services



SANDRA SHEWRY
Director



ARNOLD SCHWARZENEGGER
Governor

July 7, 2006

TO: INTERESTED PARTIES

SUBJECT: EXEMPTION TO HEALTH AND SAFETY CODE SECTION 124172
(MERCURY-CONTAINING VACCINES) FOR JAPANESE
ENCEPHALITIS VIRUS VACCINE INACTIVATED

In 2004, in order to ensure that pregnant women and children under age 3 have access to mercury-free vaccines, Governor Schwarzenegger signed AB 2943 (Pavley, Chapter 837, Statutes of 2004). Effective July 1, 2006, AB 2943 provides that vaccines containing specific levels of mercury cannot be administered to pregnant women and young children, except under certain circumstances.

While the commonly used influenza vaccine administered in the United States has an available mercury-free alternative, the more rare Japanese Encephalitis (JE) vaccine does not. The JE vaccine is only used for individuals traveling for a month or longer in certain areas of Asia and parts of Oceania. JE, a mosquito-borne infection, is the leading cause of viral encephalitis in Asia and parts of Oceania. Unimmunized children in affected areas are at highest risk of infection. Most persons with encephalitis caused by the JE virus either die or have residual neurologic disease. Infection during pregnancy may cause miscarriage. There is currently no treatment for JE. Each year, approximately 4,300 Californians (excluding military) over the age of 1 receive the JE vaccine in accordance with medical and public health recommendations.

The federal Food and Drug Administration (FDA) has licensed only one vaccine against JE for use in the United States. The formal name of the vaccine is Japanese Encephalitis Virus Vaccine Inactivated, and its trade name is JE-VAX®. It is manufactured in Japan by The Research Foundation for Microbial Diseases of Osaka University ("BIKEN®") and distributed in the United States by sanofi pasteur, Inc.

Given the absence of mercury-free JE vaccine and the risk of fatal disease or brain injury from JE, Health and Human Services Agency Secretary Kimberly Belshé exercised the authority provided by AB 2943, with concurrence from Governor Schwarzenegger, and granted an exemption from California Health and Safety Code section 124172 (a) for Japanese Encephalitis Virus Vaccine Inactivated from July 1, 2006 to June 30, 2007. This exemption will allow the JE vaccine to be administered to children younger than three years old and pregnant women to protect against severe illness or death should they visit affected areas for extended periods of time.

Secretary Belshé and Governor Schwarzenegger granted this exemption because of the health risk posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for Californians seeking protection against Japanese Encephalitis.

Governor Schwarzenegger and Secretary Belshé remain deeply committed to implementing AB 2943 and ensuring that pregnant women and young children have access to mercury-free vaccines. Based on what we know at this time, we anticipate that there should be adequate mercury-free flu vaccine for children and pregnant women for the 2006 flu season. The Governor is contacting manufacturers of mercury-free vaccines to underscore the importance of maximum production of the vaccines.

If you have any questions, please contact the California Department of Health Services Immunization Branch at (510) 620-3737.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark B. Horton', with a large, sweeping flourish extending to the right.

Mark B. Horton, MD, MSPH
State Public Health Officer